

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2007 has been entered.

### ***Amendment Entry***

2. Applicant's amendment and response filed December 20, 2007, is acknowledged and has been entered. Claims 18 and 19 have been cancelled. Claims 12 and 17 have been amended. Claims 21-24 have been added. Claims 1, 11 and 20 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1, 11, 12, 17, and 20-24 are pending.

Newly submitted claims 21-24 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: they are drawn to kits and reagent mixtures having different structural requirements, each of which are patentably distinct. As such, literature search for each of the kits and reagent mixtures is different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive, so as to provide relevant art applicable to both groups.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 1, 11, 12, 17, and 20-24 are pending. Claims 1, 11, and 20-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 12 and 17 are under examination.

### ***Withdrawn Rejections/Objections***

3. All rejections or objections not reiterated herein, have been withdrawn.
4. In light of Applicant's amendment and arguments, the rejection of claims 12 and 17 under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (Carbonic anhydrase isozymes, hemoglobin-F and glutathione levels in lead-exposed workers, *Clinica Chimica Acta: International Journal of Clinical Chemistry*, (1975 Feb 22) Vol. 59, No. 1, pp. 29-34) *in light of Funakoshi et al. (Human Carbonic Anhydrases, the Journal of Biological Chemistry 245 (11): 2852-2856 (1970)) and Tamachi (Immunological Determination of Human Fetal Hemoglobin, Z. Klin. Chem. Klin. Biochem. 11: 501-505 (1973))*, and in view of Golbus (US Patent 5,962,234), is hereby, withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in reciting, "said first and second antibodies each comprise a label for detecting reactivity of the first and second antibodies with cells by flow cytometry" because it is unclear how each label in a single kit can individually and differentially detect reactivity of each of the antibodies by flow cytometry. It appears that each of the antibodies should be distinguishably labeled for flow cytometric detection.

Claim 17 is indefinite in reciting, "said first and second antibodies each comprise a label for detecting reactivity of the first and second antibodies with cells by flow cytometry" because it is unclear how each label in a single reagent mixture can individually and differentially detect reactivity of each of the antibodies by flow cytometry. It appears that each of the antibodies should be distinguishably labeled for flow cytometric detection.

#### ***Claim Objections***

6. Claims 12 and 17 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

#### ***Remarks***

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7. Applicant requests rejoinder of the withdrawn method claims, in this case claims 1, 11, and 20, upon allowance of the product claims, pursuant to MPEP § 821.04(b).

In response, it is deemed that method claims 1, 11, and 20 are not in condition for allowance and rejoinder with claims 12 and 17 because:

1) claims 12 and 17 as recited, have pending 35 USC 112, second paragraph, issues;

2) claims 1, 11, and 20 have not been amended and fully examined on the merits for certain unresolved issues for consideration of indefiniteness under the provisions of 35 USC 112, second paragraph, consonant to the product claims; and

3) claims 1, 11, and 20 have not been amended and fully examined on the merits for certain unresolved issues for consideration of scope of enablement under the provisions of 35 USC 112, first paragraph, since the same reagent mixture appears to be able to distinguish "subsets of red blood cells in a sample" in claims 1 and 11, and "between maternal cells and fetal red blood cells in a blood sample" in claim 20, using the reagent mixture in the same method steps, without specifically and clearly defining, how each separate method should be done differentially, so as to meet the requirement of each of their preambles.

Upon amendment of claims 12 and 17 so as to obviate the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and upon amendment of withdrawn claims 1, 11, and 20 so as to obviate potential rejections under 35 U.S.C. 112, 2nd paragraph, consonant to that set forth for claims 12 and 17, as well as potential rejections under 35 U.S.C. 112, 1st paragraph, as set forth supra in paragraph number 7, item 3), reconsideration of rejoinder of claims 1, 11, and 20 for allowance with claims 12 and 17 will be forthcoming.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

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